



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,410	12/12/2000	Burkhard Goke	0206-UTL-9	8826

7590

06/05/2006

ARNOLD & PORTER

Attn: IP Docketing Department, Room 1126B  
555 Twelfth Street, NW  
Washington, DC 20004-1206

EXAMINER

MOHAMED, ABDEL A

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 06/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/719,410	<b>Applicant(s)</b> GOKE ET AL.	
	<b>Examiner</b> Abdel A. Mohamed	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 44-46 and 48-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44-46 and 48-55 is/are allowed.
- 6) ☒ Claim(s) 55-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **ACKNOWLEDGMENT TO AMENDMENT, REMARKS AND STATUS OF THE CLAIMS**

1. The amendment and remarks filed 02/14/06 are acknowledged, entered and considered. In view of Applicant's request claims 10-38 and 41 have been canceled. Claims 44-46 and 48-58 are now pending in the application. The rejections under 35 U.S.C. 102(b), 35 U.S.C. 102(a) and 35 U.S.C. 103(a) over the prior art of record have been considered but deemed to be moot in view of Applicant's cancellation of claims 10-38 and 41. The allowance of claims 55-58 of the previous Office action is withdrawn in view of the following new ground of rejection as set forth *infra*.

### **NEW GROUND OF REJECTION**

#### **CLAIMS REJECTION-35 U.S.C. § 102(b)**

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 55-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Schirra et al (J. Clin. Invest., Vol. 101, No. 7, pp 1421-1430, 1998).

The instantly claimed invention as drafted in claims 55-58 are broadly directed to a method for reducing a risk of cardiovascular event or a method for reducing a risk of

Art Unit: 1654

cerebrovascular event by administering a composition comprising an exendin, wherein said composition contains an amount of the exendin effective to enhance the regularity of insulin responses, or the amplitude thereof, in reaction to changes in plasma glucose, thereby reducing the risk of a cardiovascular event or reducing the risk of a cerebrovascular event, respectively (i.e., directed to different population than the allowed claims 44-46 and 48-54). The prior art of Schirra et al discloses the administration of exendin(9-39)amide which is a peptide receptor antagonist of GLP-1 in humans, wherein the exendin(9-39)NH<sub>2</sub> increased plasma glucagons levels during euglycemia and hyperglycemia (See e.g., last 5 lines of the abstract, Tables II and III, and Figure 4). Thus, the cited reference clearly discloses the administration of exendin at a dose effective amount to normalize blood glucose since normalizing blood glucose will inherently reduce the risk of cardiovascular or cerebrovascular events as acknowledged on page 1, lines 18-21 in the instant invention which states that subjects with impaired glucose tolerance are at high risk for the development of cardiovascular disease as well as non-insulin dependent diabetes mellitus (NIDDM), also known as Type 2 diabetes. Therefore, the cited product discloses the invention substantially as claimed, and as such provide inherent support for the administration of exendin that enhances the regularity of insulin responses to reduce cardiovascular or cerebrovascular events in patient populations who have a risk of cardiovascular or cerebrovascular event, in the absence of evidence to the contrary the exendin and its use thereof as disclosed by the prior art anticipate claims 55-5-8 as drafted.

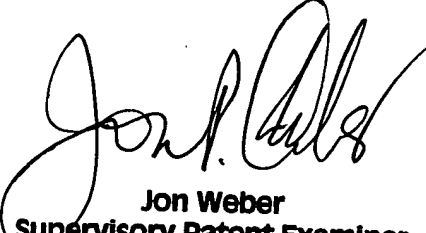
### CONCLUSION AND FUTURE CORRESPONDANCE

3. Claims 44-46 and 48-54 are allowed and claims 55-58 are rejected.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on (571) 272 0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



**Jon Weber**  
Supervisory Patent Examiner

 Mohamed/AAM  
May 22, 2006